Amendment #1
RFP-NIH-NIAID-DMID-03-06
"In Vitro Antiviral Screening Program"

Amendment to Solicitation No.:	NIH-NIAID-DMID-03-06
Amendment No.:	1 (One)
Amendment Date:	October 18, 2002
RFP Issue Date:	September 30, 2002
Proposal Due Date and Time:	January 15, 2003; 4:00 PM, EST **(UNCHANGED)**
Issued By:	Paul D. McFarlane Senior Contracting Officer NIH/NIAID Contract Management Branch 6700-B Rockledge Drive Room 2230, MSC 7612 Bethesda, Maryland 20892-7612
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This amendment replaces the Notes to Offerors with those provided below. Offerors are reminded to periodically check back to the main RFP website for any future amendments that may be made to this solicitation. This office will provide no additional notification of any amendments. Note that the date and time for proposals remains unchanged as Wednesday, January 15, 2003 at 4:00 PM Local Time.

NOTES TO OFFERORS
In Vitro Antiviral Screening Program
NIH-NIAID-DMID-03-06

NOTE TO OFFEROR (A): It is expected that 1500 experimental antiviral substances will be evaluated against orthopoxviruses and pathogens of viral hemorrhagic fever and encephalitis, 10 against human papillomaviruses, and 200 against viruses from the other viral categories annually. The drug sponsors will supply the test substances after receiving approval from the Project Officer. Acquisition of test substances will come from NIAID's TB Antimicrobial Acquisition and Coordination Facility (contract N01-AI-95364, Southern Research Institute), as well as NIAID staff with drug sponsors, and the screening contractors' contacts with drug sponsors. These substances may be irritating, toxic, and/or potentially carcinogenic or hazardous. **This note refers to Statement of Work item #1.**

NOTE TO OFFEROR (B): The Offeror shall provide validated screening systems for all of the designated viruses within the category(ies) selected. Methods of screening shall be appropriate for the assessment of the efficacy of potential therapeutic and/or prevention approaches for the proposed viruses. The methods may include, but are not limited to, plaque reduction, yield reduction, inhibition of cytopathic effect, inhibition of enzyme activity and other virus-specific assays. Assays can be manual or automatic format. Offerors shall justify the choice of method(s) proposed.] **This note refers to Statement of Work item #1.**

NOTE TO OFFEROR (C): More detailed testing will generally be required when the initial screening shows that an a substance has a substantial level of antiviral activity. The technical proposal shall describe preliminary screening procedures, the criteria used to select compounds recommended for further evaluation, and procedures for the special studies identified in Work Statement item 2. **This note refers to Statement of Work item #1.**

NOTE TO OFFEROR (D): Each special study will have distinctive evaluation needs; thus, the Project Officer will designate specific assays after consultation with the Contractors. The Offeror should include documentation of qualifications, expertise, and strategies to modify systems or develop new systems for such studies. Provide 1-2 examples of the types of special studies that could demonstrate the Offeror's capability. It is expected that special studies will be performed on no more than 30 compounds per year for orthopoxviruses and pathogens of viral hemorrhagic fever and encephalitis, one against human

papillomaviruses, and 5 against viruses from the other viral categories annually. **This note refers to Statement of Work item #2.**

NOTE TO OFFEROR (E): It is expected that no more than 10% effort of the proposed professional staff will be utilized per year to perform these evaluations. **This note refers to Statement of Work item #3.**

NOTE TO OFFEROR (F): The technical proposal shall provide detailed information about how this Statement of Work item will be addressed and identify other factors thought to be pertinent. **This note refers to Statement of Work item #4.**

NOTE TO OFFEROR (G): The technical proposal shall specify procedures that demonstrate that the Offeror understands and will comply with these Federal, State, and Local guidelines and regulations. Federal guidelines related to workplace safety can be viewed at http://www.nih.gov/od/ors/ds/safetymgt.html. A Safety and Health Plan shall be in place for compliance. The Plan shall include discussions of such topics as training and monitoring of personnel, the use of protective garments and equipment by personnel, and protocols for dealing with chemical and biological spills and accidents. The technical proposal shall also describe how to manage both short-term and long-term storage of infectious materials, receiving and shipping infectious materials and potentially hazardous chemicals, etc. **This note refers to Statement of Work item #5.**

NOTE TO OFFEROR (H): The Offeror shall, at the time of the proposal have appropriate biosafety laboratory facilities that allow research using the viruses that are assigned to the respective biosafety levels. (For reference see, Biosafety in Microbiological and biomedical Laboratories, 4th Ed., May 1999, by CDC and NIH). If the proposed virus is a BSL-3 agent, at the time of award, BSL-3 facilities must be operational. **This note refers to Statement of Work item #5.**

NOTE TO OFFEROR (I): Planned Deviations to Required General Clauses 52.227-11 and 52.227-14. **This note refers to Statement of Work item #6.** By providing information on antiviral activity developed under these contracts to suppliers of testing substances, the NIAID seeks to stimulate research and development in all sectors of the antiviral scientific community.

Because the goal of the NIAID in vitro antiviral screening program is to promote the determination of critical biological information, it will be necessary to restrict certain rights of the contractor providing in vitro testing to either attract suppliers of proprietary compositions or enable NIAID to offer a package of intellectual property rights to a collaborator for commercialization. It is anticipated that the great majority of substances submitted to the NIAID for testing will be proprietary in nature, and our experience has demonstrated that suppliers are reluctant to provide testing substances or ideas without complete assurance that their intellectual property rights are protected. In addition to the need to protect third party suppliers' proprietary rights, it is also necessary to consolidate into a single package the intellectual property rights that may arise in the performance of multiple contracts within this NIAID program.

Thus, the NIAID plans to seek a deviation from FAR clause 52.227-11, Patent Rights-Retention by the Contractor (Short Form) (June 1989). Pursuant to a Determination of Exceptional Circumstances (DEC) as required by FAR 27.303, the NIAID plans to modify clause at FAR 52.227-11, Patent Rights-Retention by the Contractor (Short Form) (June 1989) to restrict the contractor's rights to subject inventions arising under the contract. Specifically, the contractor will be required to assign to the Government or, if deemed appropriate by the NIAID and subject to certain rights reserved to the Government, to a collaborating party designated by the Government the entire right, title and interest throughout the world to each subject invention, except to the extent that rights are retained by the Contractor under the Greater Rights Determination provision of the clause. The contractor may request greater rights to an identified invention, and the NIH will consider whether granting the requested rights will interfere with rights of the Government or any collaborating party or otherwise impede the ability of the Government or others to develop new candidates for therapies, disease prevention and diagnosis as well as potential enabling technologies that may result from data ensuing from evaluations performed under this contract useful for antiviral discovery and development. Contractors are encouraged to request greater rights where inventions relate to technology outside NIAID's program and where the contractor has negotiated with a supplier of a proprietary composition for the disposition of patent rights concerning a subject invention related to the composition.

Furthermore, the timing of data publication will need to be restricted to allow adequate time for patent applications to be filed on inventions arising from the contracts. This would be accomplished by a deviation from FAR clause 52.227-14, Rights in Data-General (June 1987). Specifically, although NIAID encourages the publication of articles on research results, FAR 52.227-14 Rights in Data-General (June 1987) will be narrowly modified to restrict the Contractor's right to use, release to others, reproduce, distribute, and publish data produced or used by the contractor in the performance of this contractor to allow adequate time for the filing of patent applications and to protect data that will be submitted as part of a regulatory filing. NIAID will reserve the right to coordinate the timing of data publication so that appropriate domestic and international invention applications may be filed as appropriate.

Because these clause deviations are not yet approved, their text is not available for publication. However, it is NIAID's intention that the finalized versions of the deviated FAR clauses will be available before award of any contract resulting from this initiative. Instead, the aforementioned description of how these clause deviations will be practiced under the resultant contracts is provided. Potential Offerors are afforded an opportunity to comment on their understanding of what NIAID is planning and to identify what impact these deviations may have on their conduct of the work should they be awarded a contract. Responses should be provided, in writing, to the Point of Contact for this RFP. See the bottom of the front page of this RFP for this individual's name and contact information. Comments should be provided within 30 days of the issue date of this RFP. Thereafter, NIAID will consider this input and determine whether alternative courses of action may be necessary. Decisions regarding these deviations will be made in consideration of the success of this NIAID requirement.

NOTE TO OFFEROR (J): The technical proposal shall specify procedures to safeguard all information associated with the substances being tested, such that no identifiable data on the compounds or products nor the results of testing will be kept in files open to the public. Facilities for computer operation, data entry, and file storage should be secure from unauthorized access. **This note refers to Statement of Work item #6.**

NOTE TO OFFEROR (K): The Project Officer will review the screening report and forward it to the compound sponsor. The technical proposal shall include a template of the proposed data sheet to be included in the screening report. **This note refers to Statement of Work item #7.**

NOTE TO OFFEROR (L): Costs to support travel to the CATG and biodefense meetings for Principal Investigator, and a designated Co-Investigator (if desired), should be included in the proposed cost estimate. For estimating purposes assume that each meeting will be held for two full days in Bethesda, MD. **This note refers to Statement of Work item #7.**

Except as provided herein, all terms and conditions of the RFP document NIH-NIAID-DMID-03-06 remain unchanged and in full force and effect. Offerors must acknowledge this Amendment #1, by placing the following statement on the original and each copy of the offer submitted. "This proposal was prepared in accordance with all requirements of the solicitation and as changed by Amendment #1." Failure to provide acknowledgment of this amendment may result in the rejection of your offer.